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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Richard S. Ginn

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/734,929	Applicant(s) GINN ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 22-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/17/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 12/17/2008.

The examiner acknowledges the amendments made to the claims.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 05/21/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The last lines of Claims 1 and 11 recite the limitation "the plug member lumen". There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Freeman et al.** (U.S. Patent No. **6,306,114**) in view of **Brucker** (U.S. Patent No. **6,296,657**).

Claims 1-2 and 4-10: Freeman et al. disclose a biocompatible plug body **10** comprising a proximal end and distal end, the body comprising a lumen **18** extending between the proximal end and the distal end, and a biocompatible sealing member ("valve") **20a-e**, which may be annularly-shaped, disposed within the lumen that is expandable across the lumen when exposed to fluid for substantially sealing the lumen from fluid flow therethrough, wherein the biocompatible body does not expand when exposed to the fluid and wherein the sealing member does not extend outside the plug member lumen (see abstract; Figures 1-8). The sealing member is also biased towards a first ("closed") configuration for substantially sealing the lumen from fluid flow therethrough, and is movable to a second ("open") configuration for accommodating introduction of one or more devices through the lumen. Freeman et al. also disclose a connector on the proximal end of a biocompatible body for detachably securing the body to a delivery device or elongate member shaft **160** (Figure 14). The body has a

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length of not more than about ten millimeters and a diameter being not more than about twice the length (col. 6, lines 40-45).

Freeman et al. does not expressly disclose a bioabsorbable material for the device. However, Freeman et al. discloses a silicone, biocompatible material (col. 3, lines 65-67) and that the plug may be made of any "other suitable materials known to those skilled in the art" (col. 7, lines 11-14). Brucker also teaches a plug made of bioabsorbable materials (abstract, col. 5, lines 26-33). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a bioabsorbable material to the plug of Freeman et al., as taught by Brucker, depending on the patient and the condition if a temporary occlusion is desired without necessitating removal.

Claim 3: Freeman et al. disclose the claimed device except for the sealing member comprising an expandable gel foam.

Brucker teaches a sealing member **71** comprising an expandable gel foam that is expandable when exposed to the fluid to substantially seal the lumen (Figure 7; col. 5, lines 7-18). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the sealing member of Freeman et al. by providing an expandable gel foam that is expandable when exposed to fluid, as taught by Brucker, since it was well known in the art for facilitating selective expansion of a sealing member when placed in a wound.

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3. Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Freeman et al.** (U.S. Patent No. **6,306,114**) in view of **Brucker** (U.S. Patent No. **6,296,657**) and **Hermann et al.** (U.S. Patent No. **5,871,474**).

Claims 11-18: Freeman et al. disclose the claimed device (as mentioned above in paragraph 3), including a sealing member **20a** being disposed adjacent a wide end **22** of the lumen (see Figures 1 and 6) and being movable into a smaller diameter portion **24** of the lumen for substantially sealing the lumen from fluid flow therethrough and comprising a flexible material that may be wedged into the tapered portion (Figure 5), except for a bioabsorbable material and the lumen comprising a tapered portion that tapers in cross-section and the sealing member comprising a coil of material.

Freeman et al. does not expressly disclose a bioabsorbable material for the device. However, Freeman et al. discloses a silicone, biocompatible material (col. 3, lines 65-67) and that the plug may be made of any "other suitable materials known to those skilled in the art" (col. 7, lines 11-14). Brucker also teaches a plug made of bioabsorbable materials (abstract, col. 5, lines 26-33). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a bioabsorbable material to the plug of Freeman et al., as taught by Brucker, depending on the patient and the condition if a temporary occlusion is desired without necessitating removal.

Hermann et al. teach a plug member with a tapered lumen (Figure 6b). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a tapered lumen portion to Freeman et al. in order to better conform to the tissue passage and therefore provide a more effective sealing device. In addition,

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although the sealing member of Hermann is not comprised of a coil of material, Hermann does teach screw threads **12** which may take the form of a coil and increase the traction of the sealing member within the body to effectively keep it in place, and therefore it would have been obvious to one of ordinary skill in the art to modify the sealing member of Freeman et al. to a coil of material for increased traction and therefore a more securely sealed plug.

4. Claims 19-20, 22-25, 27-28, and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Freeman et al.** (U.S. Patent No. **6,306,114**) in view of **Brucker** (U.S. Patent No. **6,296,657**) and **Atkinson** (U.S. Patent No. **6,645,225**).

Claims 19-20, 22-25, 27-28, and 32-35: Freeman et al. disclose the claimed device (as mentioned above in paragraph 3), except for the bioabsorbable material or the plug member lumen being in fluid communication with the elongate member lumen and the plug member lumen having a tapered portion reducing in cross-section, and a second elongate member comprising a location indicator.

Freeman et al. does not expressly disclose a bioabsorbable material for the device. However, Freeman et al. discloses a silicone, biocompatible material (col. 3, lines 65-67) and that the plug may be made of any "other suitable materials known to those skilled in the art" (col. 7, lines 11-14). Brucker also teaches a plug made of bioabsorbable materials (abstract, col. 5, lines 26-33). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a bioabsorbable

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material to the plug of Freeman et al., as taught by Brucker, depending on the patient and the condition if a temporary occlusion is desired without necessitating removal.

Atkinson teaches a plug member **26** having a tapered lumen **36** being in fluid communication with an elongate member lumen **43** with cooperating connectors **44** and **38** and an actuator **46** for releasing the plug member from the distal end of the elongate member (Figure 7). It would have been obvious to one of ordinary skill in the art at the time of invention to provide communicating plug and elongate member lumens, as taught by Atkinson, to Freeman et al. in order to allow the assembled delivery combination of the elongate member and the plug to be aligned within the patient's body by sliding over an element such as a J-wire (col. 6, lines 7-11). It would have also been obvious to one of ordinary skill in the art at the time of the invention to provide a tapered portion to the plug member lumen of Freeman et al., as taught by Atkinson, in order to better conform to the tissue passage and therefore provide a more effective sealing function.

Atkinson also teaches a second elongate member **12** insertable through the plug member lumen and is disposed beyond the distal end of the plug member and acts as a location indicator (Figures 11-12; col. 4, lines 27-31). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a second elongate delivery device, as taught by Atkinson, to Brucker in order to facilitate delivery and positioning of the device into a passage through tissue.

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5. Claims 26, 31, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Freeman et al.** (U.S. Patent No. **6,306,114**) in view of **Brucker** (U.S. Patent No. **6,296,657**) and **Atkinson** (U.S. Patent No. **6,645,225**), as applied to claims 25, 27, and 33 above, and further in view of **Sepetka et al.** (U.S. Patent No. **5,814,062**).

Claim 26, 31, and 36: Freeman et al. and Brucker disclose the claimed device, including the elongate member able to move the sealing member into a smaller diameter portion of the plug member (Figures 15-16, Freeman et al.), except for an activation element coupled to the elongate member, or the elongate member comprising an expandable and collapsible engagement element engaging and disengaging an interior wall of the plug member, selectively securing to the plug member.

Sepetka et al. teach an activation element or expandable and collapsible engagement element **40** that selectively secures to a plug member **30** during delivery (Figures 4-6). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an activation element or expandable and collapsible engagement element, as taught by Sepetka et al., to Freeman et al., Brucker, and Atkinson in order to provide rapid release times and without exerting any significant force on the implant to avoid significant displacement of the plug during release (see abstract).

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Freeman et al.** (U.S. Patent No. **6,306,114**) in view of **Brucker** (U.S. Patent No. **6,296,657**) and **Atkinson** (U.S. Patent No. **6,645,225**), as applied to claim 28 above, and further in view of **Davis** (U.S. Patent No. **6,143,004**).

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Claim 29: Freeman et al., Brucker, and Atkinson disclose the claimed device, except for the second elongate member comprising a tubular member including a bleed back lumen, and wherein the location indicator comprises a bleed back port on the distal end of the tubular member, the bleed back port being in communication with the bleed back lumen.

Davis teaches a bleed back lumen **118** and bleed port **114** (Figures 6 and 8). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a bleed back lumen and port, as taught by Davis, to Freeman et al., Brucker, and Atkinson in order to easily verify proper placement of the device within the body (col. 9, lines 43-37).

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Freeman et al.** (U.S. Patent No. **6,306,114**) in view of **Brucker** (U.S. Patent No. **6,296,657**) and **Atkinson** (U.S. Patent No. **6,645,225**), as applied to claim 28 above, and further in view of **Sommercorn et al.** (U.S. Patent No. **6,494,848**).

Claim 30: Freeman et al., Brucker, and Atkinson disclose the claimed device except for an expandable member being expandable when the distal end of the second elongate member is disposed within a body lumen for providing tactile feedback of a location of the distal end of the plug member with respect to the body lumen.

Sommercorn et al. teach an expandable member **28** being expandable when the distal end of an elongate member **10** is disposed within a body lumen for providing tactile feedback of a location of the distal end of the device with respect to the body

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lumen (Figure 3). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an expandable member for tactile feedback, as taught by Sommercorn et al., to Freeman et al., Brucker, and Atkinson since the mechanism is simple to manufacture and use, as well as facilitates accurate and consistent identification when positioning plug devices during delivery (col. 3, lines 45-51)

Response to Arguments

8. Applicant's arguments with respect to claims 1-20 and 22-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734